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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|-------------------------|---------------------|------------------|
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[REDACTED] EXAMINER

BADIO, BARBARA P

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1616

DATE MAILED: 11/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|----------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/922,532 | SCHERSL ET AL. |
| Examiner | Art Unit | |
| Barbara P. Badio, Ph.D. | 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-9 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
 5) Claim(s) ____ is/are allowed.
 6) Claim(s) 1-9 is/are rejected.
 7) Claim(s) ____ is/are objected to.
 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> . | 6) <input type="checkbox"/> Other: _____ |

First Office Action on the Merits

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-9 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23-35 of copending Application No. 09/772,790. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both are drawn to compositions comprising phytosterols and policasanols and the use of said compositions in lowering serum cholesterol levels.

The difference between the claimed inventions is in the recitation of esters of policosanol in 09/772,790. However, (a) the use of esters as prodrugs and (b) increase bioavailability with the utilization of esters are known in the art. Thus, the use of esters of policosanols in the composition recited by the present claims would be *prima facie* obvious.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3, 4, 5 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Sorkin, Jr. ('393).

Sorkin teaches a composition comprising phytosterols, such as β -sitosterol, campesterol and stigmasterol and policosanols, such as docosanol, tetracosanol, hexacosanol and octacosanol for reducing serum cholesterol levels (see the entire article, especially examples 1 and 2). The reference also teaches the use of about 5% to about 75% by weight of phytosterol and about 1% to about 60% by weight of policosanol (see col. 2, lines 7-22). The composition and method of use taught by the reference are encompassed by the instant claims.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sorkin, Jr. ('393), Maurel et al. ('924) and Perez ('354) in combination.

Sorkin teaches a composition comprising phytosterols, such as β -sitosterol, campesterol and stigmasterol and policosanols, such as docosanol, tetracosanol, hexacosanol and octacosanol for reducing serum cholesterol levels (see the entire article, especially examples 1 and 2). The reference also teaches the use of about 5% to about 75% by weight of phytosterol and about 1% to about 60% by weight of policosanol (see col. 2, lines 7-22).

Maurel et al. teach phytosterols are known hypocholesterolaemic agents. The reference also teaches the incorporation of said agents in food products such as margarine (see col. 2, lines 33-46).

Perez teaches the hypocholesterolaemic property of higher molecular weight primary aliphatic alcohols such as tetracosanol, hexacosanol and octacosanol (see the entire article, especially the Abstract; col. 1, lines 15-26). The reference also teaches pharmaceutical compositions, foodstuffs and dietary supplements comprising said alcohols (see col. 7, lines 18-30).

Based on the combined teachings of the above-cited references, the combination of phytosterols and policosanols in food products for lowering serum cholesterol levels would be obvious to one having ordinary skill in the art. The motivation to add said

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combination to food products is based on the desire to find safe and tolerated means for administration of pharmaceutical agents such as hypocholesterolaemic agents to patients.

Other Matters

7. Claim 1 contains double recitation of the phrase "one or more component selected from the group consisting of octadecanol, eicosanol, docosanol, tetracosanol and hexacosanol". It is assumed said is a typographical error. Correction is requested.

Telephone Inquiry

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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Barbara Padio
Barbara P. Padio, Ph.D.
Primary Examiner
Art Unit 1616

BB

November 26, 2002